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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,618	12/06/2001	Olga Bandman	PF-0200-1 DIV	1376

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INCYTE CORPORATION
3160 PORTER DRIVE
PALO ALTO, CA 94304

EXAMINER	
HUFF, SHEELA JITENDRA	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 04/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/020,618	BANDMAN ET AL.	
	Examiner	Art Unit	
	Sheela J Huff	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,11-13,16-27,30,31,36,39,44 and 45* is/are pending in the application.

4a) Of the above claim(s) *11-13,16-27,30,31,36,39,44 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-2 in Paper No. 03/18/04 is acknowledged. The traversal is on the ground(s) that rejoinder should be considered and that there is no undue burden. This is not found persuasive because as stated in the restriction requirement, rejoinder will be considered at the appropriate time and there is undue burden for the reasons of record.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The IDS filed 12/6/01 has been considered and an initialed copy of the PTO-1449 is enclosed.

Claim Rejections - 35 USC § 112

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to naturally occurring polypeptides having 90% identity with SEQ ID no. 1 and biologically active fragments of Seq ID NO.1. While the amino acid sequence of SEQ ID NO:1 is adequately described in the specification as-filed, thereby providing an adequate basis for the polypeptide of SEQ ID NO:1; there is insufficient written description as to the identity of a polypeptide having at least 90% sequence identity to SEQ ID NO:1 or fragments thereof that would still maintain the

function of the polypeptide. Consequently, the specification does not provide an adequate written description of a polypeptide having at least 90% sequence identity to SEQ ID NO:1 or fragments thereof.

The specification as filed does not provide adequate written description support for a polypeptide having at least 90% sequence identity to SEQ ID NO:1. Polypeptides having diverse functions are encompassed by the phrase at least 90% identity. Thus a broad genus having potentially highly diverse functions is encompassed by the phrase 90% sequence identity" and conception cannot be achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. For example, Skolnick et al. (Trends in Biotech., 18(1):34-39, 2000) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2). Adequate written description requires more than a mere statement that it is part of the invention. The sequence itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

With respect to naturally occurring, this terminology reads on allelic variants. Reiger et al (Glossary of Genetics and Cytogenetics, Classical and Molecular, 4th Ed.,

Springer-Verlay, Berlin, 1976) clearly define alleles as one of two or more alternative forms of a gene occupying the same locus on a particular chromosome..... and differing from other alleles of that locus at one or more mutational sites (page 17). Thus, the structure of naturally occurring allelic sequences are not defined. With the exception of the polynucleotide that encodes SEQ ID No. 1 , the skilled artisan cannot envision the detailed structure of the allelic variants and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

With respect to biologically active fragments, applicant has not provided any guidance as to which domains of the sequence would be considered active. Are the active sites conformational or linear? Insufficient written description is given with respect to biologically active fragments.

Therefore, only SEQ ID No. 1 meets the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 is drawn to a polypeptide comprising at least an immunogenic portion of SEQ ID NO. 1. These portions are to be contained in compositions that invoke an immunogenic response. However, all portions of the SEQ ID No. 1 cannot be deemed immunogenic. It is not clear if any portion of the protein can be used for instance to induce a variety of cytokines that affect general host responses. The specification has not presented evidence of the use of an immunogenic portion of a protein, nor has the specification clearly distinguished how one of ordinary skill in the art could identify the presence of a unique, highly antigenic protein or how to use them. The attached review authored by Walter (Journal of Immunological Methods 88:149-161, 1986) discusses the selection of potential antigenic determinants and the considerations required to

identify potential immunogens. An effective immune response (i.e. generation of antibodies) is dependent upon criteria suggested by Walter. Undoubtedly, there needs to be a correlation between for instance the conformation, the hydrophilicity and the size of the alleged immunogenic portion.

Applicants have not defined what amino acid residues are clearly immunogenic, nor presented objective evidence that supports the use of these portions in assays, for example that analyze either T-cell or antibody responses of patients against autologous cells or define predicted immunogenic epitopes. It is not clear that any immunogenic portion of Applicants' protein would even generate a modest immune response or how to generate relatively potent immune responses. Hence, there is lack of instruction in the specification enabling one skilled in the art to make and practice the invention commensurate within the scope of the claim utilizing immunogenic portions of a protein. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art. For the above reasons, it appears that undue experimentation would be required to use the claimed invention.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6294657 is cited as being pertinent art. Applicant is directed to SEQ ID NO. 12 in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Tuesday 5:30am-11:30am and Fridays 6:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheela J Huff
Primary Examiner
Art Unit 1642

sjh